Substitute for form 1449A/PTO (modified)

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Page 1 of 1

Application Number	10/630414	
Filing Date	July 30, 2003	
First Named Inventor	Wu, Zheng Z.	
Confirmation Number	9005	
Attorney Case Number	54334US019	

	U.S. Patent Documents					
Exam.	Cite	Document Number	Publication Date	Name of Patantee	Pages, Columns, Lines, Where Relevant Passages or Relevant	
Init.*	No.	Doc. Number-(Kind Code if Known)	MM-DD-YYYY	or Applicant of Cited Document	Figures Appear	
	A1	US-				
	A2	US-				
	АЗ	US-				
	A4	US-				
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	A8	US-				
	A9	US-				
	A10	US-				
-	A11	US-				
	A12	US-				

	Foreign Patent Documents						
Exam.	Cite	Cite Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages	Translation	
init.*	No.	Ctry. Code	Number-KindCode (if known)	MM-DD-YYYY	Applicant of Cited Document	or Relevant Figures Appear	(Check if yes)
/MH/	B1	EP	1 157 689 A1	28-11-2001			
	B2						
	В3						
	B4						
	<b>B</b> 5						
	В6						
	B7						

	OTHER DOCUMENTS				
Exam. Init.*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, Catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	Translation (Check if yes)		
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*Examiner:	/Mina Haghighatian/	Date Considered:	09/10/2007
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of

	Complete if Known		
Application Number	10/630,414		
Filing Date	July 30, 2003		
First Named Inventor	Zheng Z. WU, et al.		
Art Unit	1616		
Examiner Name	Mina Haghighatian		
Attorney Docket Number	r 03196-0072-01000		



		U.S. PATENTS	AND PUBLISH	D U.S. PATENT APPLICAT	IONS
Examiner Initials	Cite No. <sup>1</sup>	Document Number  Number-Kind Code <sup>2</sup> (# known)	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/MH/		US-3,361,306	01/02/1968	Grim	
		US-3,622,053	11/23/1971	Ryden	
11		US-4,185,100	01/22/1980	Rovee et al.	
		US-4,499,108	02/12/1985	Sequeira et al.	
		US-4,579,854	04/01/1986	lwakuma et al.	
1		US-4,835,145	05/30/1989	MacDonald	
<u> </u>		US-5,192,528	03/09/1993	Radhakrishnan et al.	
1		US-5,415,853	05/16/1995	Hettche et al.	
		US-5,435,297	07/25/1995	Klein	
		US-5,605,674	02/25/1997	Purewal et al.	
1		US-5,642,728	07/01/1997	Andersson et al.	
_		US-5,653,961	08/05/1997	McNally et al.	
		US-5,676,930	10/14/1997	Jager et al.	
		US-5,683,677	12/09/1997	Purewal et al.	
		US-5,695,743	12/09/1997	Purewal et al.	
	-	US-5,891,419	04/06/1999	Cutie et al.	
		US-5,954,047	09/21/1999	Armer et al.	
		US-5,955,058	09/21/1999	Jager et al.	
		US-6,004,537	12/21/1999	Blondino et al.	
		US-6,026,808	02/22/2000	Armer et al.	
		US-6,045,778	04/04/2000	Jager et al.	
		US-6,045,784	04/04/2000	Ruebusch et al.	
		US-6,131,566	10/17/2000	Ashurst	
		US-6,150,418	11/21/2000	Hochrainer et al.	
		US-6,241,969	06/05/2001	Saidi et al.	
		US-6,253,762	07/03/2001	Britto	
		US-6,290,930	08/18/2001	Blondino et al.	
		US-2001/0031244 A1	10/18/2001	Lewis et al.	
/MH/		US-6,413,496	07/02/2002	Goodman et al.	

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Examiner Signature	/Mina Haghighatian/	Date Considered 09/10/2007	

/MH/	US-6,451,285	09/17/2002	Blondino et al.	
	US-2003/0066525 A1	04/10/2003	Lewis et al	Duplicate
/MH/	US-2003/0077230	04/24/2003	Blondino et al.	
1	US-2003/0157028 A1	08/21/2003	Lewis et al.	
	US-2003/0190287 A1	10/09/2003	Lewis et al.	
	US-2003/0190289 A1	10/09/2003	Lewis et al.	
1	US-2003/0206870	11/06/2003	Lewis et al.	
	US-6,645,466	11/11/2003	Keller et al.	
1	US-2004/0047809 A1	03/11/2004	Lewis et al.	
	US-6,713,047 B1	03/30/2004	Lewis et al.	
	US-2004/0062720 A1	04/01/2004	Lewis et al.	
	US-6,716,414 B2	04/06/2004	Lewis et al.	
1 1	US-2004/0096399 A1	05/20/2004	Lewis et al.	
	US-2004/0184993 A1	09/23/2004	Lewis et al.	
	US-2005/0129621 A1	06/16/2005	Davies et al.	
	US-2005/0142071	06/30/2005	Lewis et al.	
1	US-2005/0152846 A1	07/14/2005	Davies et al.	·
1 1	US-2005/0154013 A1	07/14/2005	Davies et al.	
	US-2005/0220718 A1	10/06/2005	Lewis et al.	
	US-6,964,759	11/15/2005	Lewis et al.	
	US-7,018,618	03/28/2006	Lewis et al.	
	US-2006/0083693	04/20/2006	Lewis et al.	
	US-2006/120966 A1	06/08/2006	Church et al.	·
	US-2005/0165603 A1	07/27/2006	Meakin et al.	
	US-2006/0257324 A1	11/16/2006	Lewis et al.	
/MH/	US-7,223,381 B2	05/29/2007	Lewis et al.	

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete If Known			
Application Number	10/630,414		
Filing Date	July 30, 2003		
First Named Inventor	Zheng Z. WU, et al.		
Art Unit	1616		
Examiner Name	Mina Haghighatian		
Attorney Docket Number	03196-0072-01000		

		FORE	GN PATENT	DOCUMENTS		
Examiner Initials	Cite No.'	Foreign Patent Document  Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>6</sup> (# known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation <sup>6</sup>
/MH/		GB 1 525 181	09/20/1978	Syntex Inc.		
		EP 0 372 777 A2	06/13/1990	Purewal et al.		
		WO 91/11173	08/08/1991	Steele et al.		
_		WO 92/11236	07/09/1992	Milosovich et al.		
		EP 0 504 112 A2	09/16/1992	Herzog et al.		Abstract
		WO 92/20391	11/26/1992	Adjel et al.	<u> </u>	
		WO 93/05765	04/01/1993	Mistry et al.		
_		WO 93/11743	06/24/1993	Akehurst et al.		
	<b></b>	WO 93/11747	06/24/1993	Schultz et al.		
1		WO 93/18746	09/30/1993	Hettche et al.		Abstract
	<u> </u>	WO 94/13262	06/23/1994	Jager et al.		
		WO 94/14490	07/07/1994	Hugemann et al.		
	<del></del>	WO 94/21228	09/29/1994	Duan et al.		
	<del> </del>	WO 94/21229	09/29/1994	Duan et al.		
<b>—</b>		EP 0 653 204 A2	05/17/1995	Purewal et al.		
		WO 95/17195	06/29/1995	Tzou et al.		
	<b></b>	WO 96/18384	06/20/1996	Sapsford		
		WO 96/19198	06/27/1996	Bäckström		-
		WO 96/19968	07/04/1996	Green	<u> </u>	
		WO 96/19969	07/04/1996	Otterbeck et al.		Abstract
		WO 96/32150	10/17/1996	Ashurst et al.		
		WO 97/47286	12/18/1997	Oliver et al.		<u> </u>
		WO 98/01147	01/15/1998	Bell		<u> </u>
		WO 98/03533	01/29/1998	Arrow et al.		
		WO 98/05302	02/12/1998	Miller et al.		
		FR 2 756 502	06/05/1998	De LaForcade		Abstract
/MH/	<b> </b>	WO 98/34595	08/13/1998	Keller et al.		

Examiner	/Mina Haghighatian/	Date	09/10/2007
Signature		Considered	

Complete if Known IDS Form PTO/SB/08: Substitute for form 1449A/PTO Application Number 10/630,414 Filing Date July 30, 2003 INFORMATION DISCLOSURE First Named Inventor Zheng Z. WU, et al. STATEMENT BY APPLICANT Art Unit 1616 (Use as many sheets as necessary) Mina Haghighatian Examiner Name 03196-0072-01000 Attorney Docket Number Sheet 5

/MH/	WO 98/34596	08/13/1998	Stefely, et al.	
1	WO 98/56349	12/17/1998	Lewis et al.	
1	GB 2 326 334 A	12/23/1998	Ventura et al.	
1	WO 99/12596	03/18/1999	Chiesi et al.	
+ +	EP 0 911 048 A2	04/28/1999	Armer et al.	
1	WO 99/64014	12/16/1999	Ekström	
	WO 96/65460	12/23/1999	Blondino et al.	
1	WO 99/65464	12/23/1999	McNamara et al.	
1 1	WO 00/06121	02/10/2000	Keller et al.	Abstract
	WO 00/07567	02/17/2000	Keller et al.	Abstract
1	WO 00/23065	04/27/2000	Hochrainer et al.	Abstract
	WO 00/35458	06/22/2000	Blondino et al.	
+	WO 00/53157	09/14/2000	Musa et al.	
<del>- </del>	WO 00/78286 A1	12/28/2000	Wu et al.	
/MH/	WO 01/47493 A1	07/05/2001	Cripps, et al.	

Examiner Signature	/Mina Haghighatian/	Date Considered	09/10/2007

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INFORMATION DISCLOSURE				Filing Date	July 30, 2003	
STATEMENT BY APPLICANT				First Named Inventor	Zheng Z. WU, et al.	
			AIN I	Art Unit	1616	
	(Use as many sheets	as necessary)		Examiner Name	Mina Haghighatian	
Sheet	5	of	5	Attorney Docket Number	03196-0072-01000	

		NONPATENT LITERATURE DOCUMENTS	
Initials No.1 (book, magazine, journal, serial, sympoblisher, control of the initials No.1 (book, magazine, journal, serial, sympoblisher, control of the initial of the in		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation
		Tsi-Zong Tzou et al., "Drug Form Selection in Albuterol-Containing Metered-Dose Inhaler Formulations and Its Impact on Chemical and Physical Stability", Journal of Pharmaceutical Sciences, 1997, Vol. 86, No. 12, pp. 1352-1357	
		S.S. Davis, "Physico-Chemical Studies on Aerosol Solutions For Drug Delivery I. Water-Propylene Glycol Systems", International Journal of Pharmaceutics, 1, 1978, pp. 71-83	
		R.O. Williams, III, et al., European Journal of Pharmaceutics and Biopharmaceutics, Vol. 44, pp. 195-203 (1997)	
		Paul A. Sanders, Ph.D., "Homogeneous Systems and Their Properties", Handbook of Aerosol Technology, Second Edition, Van Nostrand Reinhold Company, NY, pg. 30, 1979	
		P. Hoet et al, "Epidemic of liver Disease Caused by Hydrochlorofluorocarbons Used as Ozone-Spring Substitutes of Chlorofluorocarbons", The Lancet, 1997, Vol. 350, pp. 556-559	
		M.J. Kontny et al, "Issues Surrounding MDI Formulation Development with Non-CFC Propellants", Journal of Aerosol Medicine, 1991, Vol. 4, No. 3, pp. 181-187	
		L.I. Harrison et al, "Pharmacokinetics and Dose Proportionality of Beclomethasone From Three Strengths of A CFC-Free Beclomethasone Dipropionate Metered-Dose Inhaler", Biophamaceutics & Drug Disposition, 1997, Vol. 18, No. 7, pp. 635-643	
		L. Harrison et al, "Twenty-eight Double-blind Safety Study of an HFA-134a Inhalation Aerosol System in healthy Subjects", J. Pharm. Pharmacol., 1996, Vol. 48, pp. 596-600	
		J. Daly, Jr., "Properties and Toxicology of CFC Alternatives", Aerosol Age, February 1990, pp. 26-27, 40, 56 and 57	
		I.P. Tansey, "Changing to CFC-Free Inhalers: The Technical and Clinical Challenges", The Pharmaceutical Journal, 1997, Vol. 259, pp. 896-898	
		Handbook of Pharmaceutical Exicipients, 3rd Ed., (2000) Kibbe Editor, PP. 7-9, 220-222, 234-235 and 560-561	
		G. Brambilla et al, "Modulation of Aerosol Clouds Produced by HFA Solution Inhalers", Portable Inhalers, pp. 155-159, (November 26 & 27, 1998)	
		D. Tiwari et al., "Compability Evaluation of Metered-Dose Inhaler Valve Elastomers with Tetrafluoroethane (P134a), a Non-CFC Propellant, Drug Development and Industrial Pharmacy, 1998, Vol. 24, No. 4, pp. 345-352	
		D. Strobach, "Alternatives to CFCs" Part III, Aerosol Age, July 1988, pp. 32-33, 42 and 43	
		Chet Leach, "Enhanced Drug Delivery Through Reformulating MDIs with HFA Propellants-Drug Deposition and Its Effect on Preclinical and Clinical Programs", Respiratory Drug Delivery V, 1996, pp. 133-144	
		B. Meakin, "Fine Particle Dose Control of Solution Based pMDIs", Drug Delivery to the Lungs IX, The Aerosol Society, pp. 1-20, (December 14 & 15, 1998)	
/MH/		ABPI Compendium of Data Sheets and Summaries of Product Characteristics, Datapharm Publications Limited, London, pp. 81-82, (1996-1997)	

Examiner /Mina Haghighatian/	Date Considered	09/10/2007
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